LAKE MEAD NATIONAL RECREATION AREA
RESOURCE MANAGEMENT DIVISION

QUALITY SYSTEM MANAGEMENT PLAN FOR ENVIRONMENTAL DATA COLLECTION PROJECTS

Draft (5/06/2002)

by

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CONTENTS

Pages

LIST OF FIGURES

LIST OF TABLES

SECTION 1.0

QUALITY SYSTEM MANAGEMENT PLAN IDENTIFICATION FORM

Document Title:	Quality System Management Plan for Environmental Data Collection Projects
Document Control Number:	N/A
Organization Title:	Resource Management Division Lake Mead National Recreation Area National Park Service 601 Nevada Highway Boulder City, Nevada 89005-2426
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Plan Coverage:	All Lake Mead National Recreation Area (LAME) Resource Management Division projects that include environmental data collection efforts. Included also are studies conducted by outside investigators at LAME for which permission to collect environmental data is granted by the Resource Management Division. Projects excluded from the scope of this plan include work performed under the Cultural Resources Branch, unless otherwise required.

1.1 CONCURRENCES

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SECTION 2.0

INTRODUCTION

This Quality System Management Plan (QSMP) was prepared to provide guidance to project leaders and project participants of the Resource Management Division (RMD) at the Lake Mead National Recreation Area (LAME) during environmental data collection activities. This guidance has been prepared to conform to the American National Standard (ANSI/ASQC E4-1994), "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs[1]."

All RMD projects (other than those exempted in Section 1.0) must comply with the RMD quality system set forth in this document. The quality system at this time may not provide adequate guidance for some RMD studies and it is this type of improvement that should be remedied in the annual revision exercise described in Section 13. A copy of this QSMP will be provided to each project leader and project participant from the RMD.

Since RMD management and project leaders are responsible for the implementation of QA, these individuals are involved in the development, review and revision of this document. This QSMP describes the structure of the quality system defining specific roles, responsibilities, and authority. The QSMP also lists resources available for performing QA and what activities should be performed before, during, and after data collection. Guidelines for preparing Resource Management Project Plans and Standard Operating Procedures are presented.

The authors wish to acknowledge the assistance of Amy Cross-Smiecinski, a quality assurance manager at the Harry Reid Center for Environmental Studies, with the preparation of this document. Several sections of this plan have been adapted directly from her 1998 report entitled "Quality Assurance Program for Scientific Investigators[3]." Mike Boyles of the RMD provided the photograph on the cover page.

SECTION 3.0

QUALITY ASSURANCE POLICY STATEMENT

Lake Mead National Recreation Area (LAME) staff collect a variety of data on physical resources, wildlife, vegetation, cultural heritage, and resource management. Park personnel use these data to assist in natural resource management and the preservation of cultural heritage sites. Additional data collection activities are currently being planned to address the need for information on the effectiveness of ongoing and designed restoration activities as well as the development of a vital signs program for the park. It is therefore important to develop scientifically valid databases that serve to improve our understanding of the current status and trends in the condition of these important natural resources.

3.1 COMMITMENT

The Resource Management Division (RMD) is committed to the achievement of quality for all of its project activities. It is the policy of the RMD that products resulting from its activities meet the highest standards.

To fulfill this commitment, the RMD has established organizational responsibilities, including Project Leaders, and a QA Manager, to ensure that quality is integrated into appropriate RMD studies. Management is committed to providing adequate resources and sufficient authority to staff to enable them to plan, implement, assess and improve the RMD quality system effectively.

The achievement of quality is the responsibility of all personnel assigned to a project. Because time and cost as well as health and safety are realistic constraints at RMD, planning to achieve quality with care and without waste is top priority. Activities that support the production of quality data, such as training, recognition of performance, identification of problems, and verification of solutions, are supported in RMD's quality system. The guidelines presented here constitute the basis for RMD's commitment to quality.

3.2 POLICY

A quality system has been established to ensure that all data collected are scientifically sound, of known quality and thoroughly documented. This quality system applies to all scientific and technical work conducted for the RMD in LAME and included all field and laboratory data gathering activities involving the determination of biological, physical or chemical factors related to the environment.

The management of the RMD is dedicated to the encouragement of excellence in measurement activities and seeks to provide the physical and mental environment conducive to its achievement. To this end, QA will be an integral component of all resource management activities that generate or use environmental related measurement data.

During the planning, implementation and assessment of projects undertaken by the RMD, several QA activities will be undertaken. Realistic measurement quality objectives will be established during the planning phase and experimental design of the project. A Resource Management Project Plan (RMPP) will be developed to achieve these objectives. Standard operating procedures will be prepared and field or laboratory staff will be trained and certified to conduct these procedures. An independent field or laboratory audit will be undertaken to ensure that these procedures are being followed. All data collected will be reviewed (checked for data transcription errors) and verified (e.g. checking for internal data consistency). Data quality will be assessed through a remeasurement

program to provide estimates of precision (at a minimum) and bias, comparability, completeness, and detectability (as appropriate).

A continual improvement process will be undertaken to ensure that all data collected for the RMD are more than adequate for their intended purpose and have been collected in cost effective manner

.

The following RMD QA policies will be implemented for each project as applicable (See Section 1.0, plan coverage):

* An approved Resource Management Project Plan is to be written by the Project Leader.

* Standard operating procedures (SOPs) shall be prepared following the criteria in Section 11.1.

* The authority to conduct independent internal QA assessments of projects is delegated to the QA manager.

* RMD data will be supported when applicable by appropriate QA and quality control (QC) criteria and documentation to ensure that all data collected, stored, reported, or used by RMD are scientifically sound, defensible, and of adequately known precision and accuracy and are representative, complete, and comparable when appropriate.

* This QSMP shall be reviewed at least once per year and updated if necessary. If it is found upon review that no revision is necessary, this conclusion will be documented in the QSMP file in the QA staff files containing the original signed document.

SECTION 4.0

MANAGEMENT AND ORGANIZATION

4.1 INTRODUCTION

An organizational chart is presented in Figure 1. The QA manager, who acts in an advisory capacity only, reports to the RMD Chief who has the authority to direct any corrective action that may be needed of staff. The QA manager also interacts directly with and provides QA advice and assistance to the RMD Project Leaders and other staff in the same manner, but has no direct authority over them. The RMD Project Leaders report to the RMD Branch Chiefs or the RMD Chief, with the project participants reporting to the Project Leaders for each study.

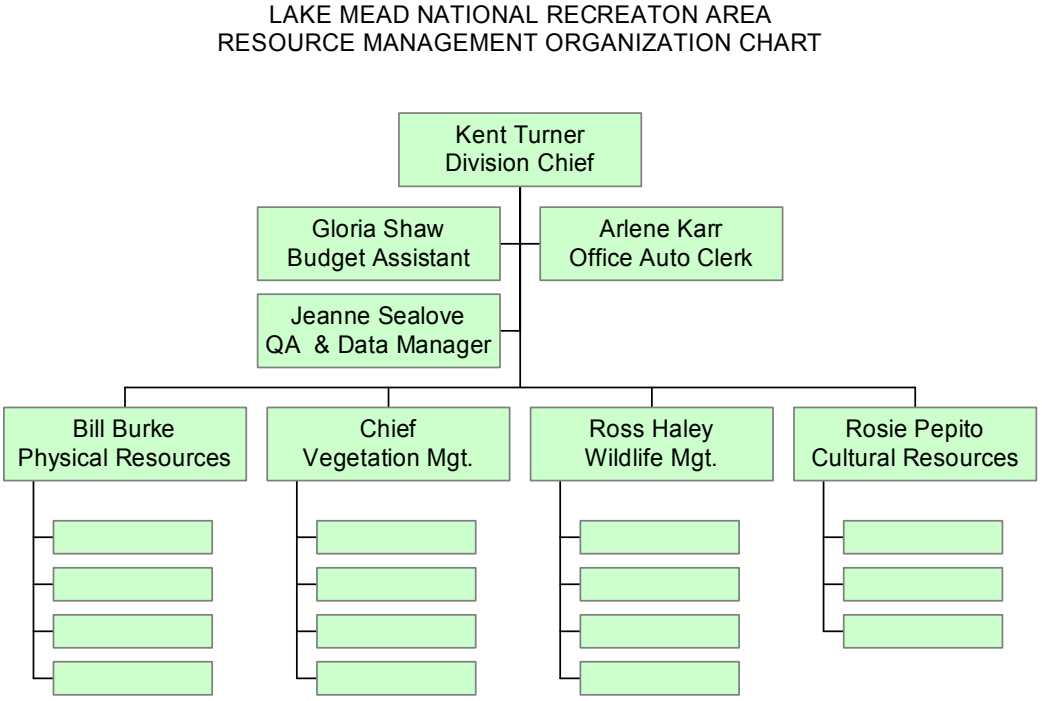


Figure 1. Organization chart for the Resource Management Division

The RMD management and technical staff share the responsibility for implementing the QA policies and are accountable for those aspects of QA/QC associated specifically with their work areas. Specific responsibilities follow.

4.2 INDIVIDUAL RESPONSIBILITIES

4.2.1 Resource Management Division Chief and Branch Chiefs

The RMD Chief may delegate authority for planning, accomplishing, and assessing the quality system to other individuals. However, the RMD Chief will retain overall responsibility for managing the RMD quality system in accordance with RMD policy. Branch chiefs are responsible for implementing the quality system within their branches.

4.2.2 Quality Assurance Manager and QA Team

The QA Manager serves as a consultant and auditor and is available to all RMD personnel in QA matters. The QA manager can organize a QA team from the division to assist with these duties. These responsibilities include:

* Assisting and advising the RMD in the planning, management, and coordination of QA.

* Advising management in the establishment and modification of RMD policy for QA.

* Working with and advising project leaders during definition and development phases of the studies, defining QA needs and assisting to formulate RMPP s.

* Recommending the need for corrective action on the basis of formal audit reports, or informal consultations with project personnel.

* Reviewing RMPP s, work plans or protocols, data reports, standard operating procedures, proposals, and any other QA-related documents. Such reviews may be either informal or part of formal audits.

* Serving as the RMD QA liaison to the National Park Service and participating in QA-related activities, meetings, etc.

* Reviewing and evaluating the QA status of each project at the RMD as applicable.

4.2.3 RMD Project Leader

The project leader is responsible for the management of the project and the resulting reports and deliverables. Therefore, the Project Leader has the primary responsibility for ensuring that project objectives are met. The Project Leader s responsibilities to the quality system include:

* Document control including the preparation, review, approval, issuance, and control of the Resource Management Project Plan (RMPP) and Standard Operating Procedures (SOPs) as well as scientific notebooks.

* Reviewing and evaluating the quality of research outputs generated for the project.

* Implementing corrective actions.

* Establishing planning policies to ensure that adequate resources are included in studies for QA activities.

* Implementation of the QA activities and SOPs and taking any indicated corrective actions to assure compliance with requirements.

* Establishing project objectives, such as measurement quality objectives, specifications, and acceptance criteria for the project's results.

* Reporting major problems and progress to the RMD branch chief or division chief.

* Reviewing and evaluating the QA status of each project under his or her management.

4.2.4 Project Participants

Each individual project participant is responsible for the quality of the results generated from his or her task. These responsibilities include:

* Preparing and delivering QA outputs and evaluation reports.

* Following standard operating procedures in the field or laboratory.

* Coordinating or performing and documenting preventive as well as service maintenance.

* Taking corrective action.

* Documenting variations and nonstandard procedures and methods.

* Establishing and maintaining project QA requirements and desired outputs based on work plans and directives.

* Reporting all problems and corrective actions to the project leader.

* Recommending managerial corrective actions.

4.3 COMMUNICATIONS

RMD project communications follow the organizational scheme described in section 4.1 with informal information flowing freely among the RMD chief, Branch Chiefs, Project Leaders, Project Participants , and the QA manager. Formal communications are recorded in written documents.

4.4 QUALITY SYSTEM IMPLEMENTATION

It is recognized that the overall objective of this plan is to establish a formalized quality system for environmental data collection efforts in the LAME Resource Management Division. As a new effort, it is anticipated that the implementation of this plan will, of necessity, be gradual.

The following steps will be taken to encourage the rapid implementation of the quality system:

* a training program will be established to provide RMD staff with a basic understand of QA concepts and procedures;
* several ongoing RMD projects will be selected as pilot studies for the testing of recommended QA activities from this plan;
* a revision to this QMSP will be undertaken on an annual basis to incorporate recommended improvements based upon lessons learned from the implementation of this plan through pilot studies;
* a goal for full compliance with this plan (as modified) is 18 months from its initial signed acceptance.

It is anticipated that differences of opinion regarding technical issues (e.g., data quality assessments, audits)

and management issues (e.g., staffing, management review) will arise. Disagreements should be resolved at the lowest administrative level possible. Issues that are deemed irresolvable at these levels should be described in detail and forwarded to the RMD Chief for resolution.

SECTION 5.0

QUALITY SYSTEM DESCRIPTION

The quality system can be divided into elements that support the overall quality system and QA activities that are required during the planning, implementation, assessment and continual improvement phases of a project. A graphic representation of this division is shown in Figure 2.

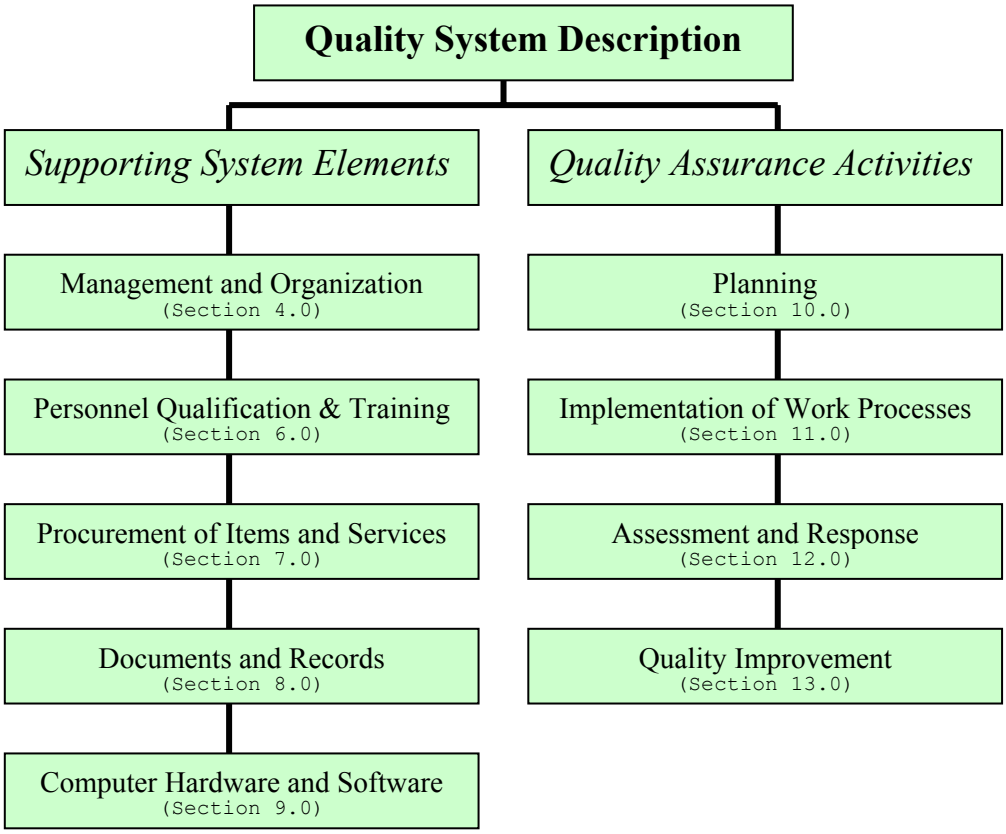


Figure 2. Components of the RMD quality system

The supporting elements are described in Section 4 (Management and Organization), Section 6 (Personnel Qualification and Training), Section 7 (Procurement of Items and Services), Section 8 (Documents and Records), and Section 9 (Computer Hardware and Software). The quality assurance activities required during the implementation of the RMD quality system are described in Section 10 (Planning), Section 11 (Implementation of Work Processes), Section 12 (Assessment and Response) and Section 13 (Quality Improvement). A short summary of these activities with the associated QA tools and personnel responsibilities are presented in Table 1.

Table 1. Quality assurance activities, tools and responsibilities for the RMD quality system

Project Phase	*Activity*	*Tools*	*Responsibility*
Planning	Develop a project plan with a QA section	Resource Management Project Plan (RMPP)	Prepare: Project Leader Review: QA Team
	Select measurement quality objectives (MQO's)	Resource Management Project Plan (RMPP)	Prepare: Project Leader Review: QA Team
Implementation	Develop detailed methods and data quality objectives	Standard operating procedures (SOP's)	Prepare: Project Leader Review: QA Team
	Conduct training and certification of trainees	Training guide and certification forms	Prepare: Project Leader Review: QA Team
	Collect, record and control data	Scientific notebooks, field forms, data recorders	Prepare: Project Leader Review: QA Team
	Collect and control samples (if required)	Sample labels and sample handling procedures	Prepare: Project Leader Review: QA Team
	Calibrate and maintain field and laboratory equipment	Standard operating procedures (SOP's)	Prepare: Project Leader Review: QA Team
Assessment and Response	Conduct audits	Field audit form	Prepare: Project Leader Review: QA Team
	Remeasurements	Field data collection forms, remeasurement schedule	Prepare: QA Manager Conduct: Auditors, QA remeaurement crew
	Data review, verification and validation	Data entry checks, illegal data filters, outlier detection, internal consistency checks	Prepare: Project Leader Program: Data Manager Conduct: Project Team
	Assess quality of data	Quality assessment section in project reports	Prepare: Project Leader Review: QA Manager
Continual improvement	Conduct annual reviews of project	Debriefing reports, client interviews: system audits	Prepare: Project Leader Review: QA team

SECTION 6.0

PERSONNEL QUALIFICATION AND TRAINING

It is the policy of the RMD that all personnel colleting environmental data be trained and qualified to collect project specific data prior to the start of that activity. In addition, all personnel should receive training regarding the RMD quality system and the importance of complying with RMD quality system requirements. The RMD quality manager is responsible for providing this training on a periodic basis.

Required qualifications of personnel involved in a project shall be described. Resumes of key task personnel shall be included in the RMPP as an appendix or otherwise documented in project files. Specific required training; its timing relative to tasks; as well as the provision for training documentation shall be identified.

All RMD personnel shall be hired under LAME Policy using the salary ranges specified in that system. Personnel shall be selected who meet at least the qualifications or position descriptions specified for each project as applicable.

The performance of all RMD professional personnel shall be reviewed on a regular basis as applicable and if required by LAME. When job requirements change, additional training will be provided to ensure personnel job proficiency.

SECTION 7.0

PROCUREMENT OF ITEMS AND SERVICES

7.1 GENERAL PURCHASING REQUIREMENTS

Measures shall be established to insure that purchased material, equipment, and services are complete and conform to LAME procurement documents.

7.2 PROCUREMENTS

Most equipment and materials purchased by RMD are commercial grade items (catalog items). Procurement activities at RMD, including supplier selection, are controlled through the LAME purchasing department. RMD personnel will initiate purchases for equipment and materials in accordance with LAME purchasing procedures. Procurement documents for these items will identify the product by the manufacturer's published product description. Procured services such as calibration services and subcontracts must operate to the appropriate level of quality. To ensure this, staff must ensure QA requirements are passed down to vendors.

Project Leaders must make provisions to assure that items ordered are the items received, and documentation as applicable to the item, was received and is acceptable. Conformance to quality specifications described in procurement documents will be evaluated. Items that do not meet purchasing requirements should be documented, evaluated, identified, and segregated to prevent inadvertent use.

Outside investigators may be contracted to collect environmental data at LAME. Each project shall have an approved RMPP prior to the initiation of data collection. This RMPP shall be reviewed and approved by the RMD Quality Manager and the Branch Chief or assigned resource specialist for the subject area of the project.

Outside investigators may also request permission to collect environmental data at LAME at their own expense. As with contracted activities, each proposed project plan will be reviewed by the RMD quality manager and a Branch Chief or assigned resource management specialist. Quality system deficiencies in project plans will be addressed prior to granting approval for data collection activities.

SECTION 8.0

DOCUMENTS AND RECORDS

8.1 SCIENTIFIC NOTEBOOKS

Scientific notebooks are used for documenting activities not defined in SOPs. Scientific notebooks will be maintained as specified in SOP(s) and will contain or reference, as appropriate, the following technical information:

* a description of the work performed;
* names and dates of individual(s) performing the work and/or making the entries;
* initial method and any changes to the methods used or references thereto;
* a description of the equipment used, including manufacturer, model, and serial number;
* SOPs and equipment manuals used;
* calibration status of equipment;
* identification of data acquisition computer hardware and software, including software title and version;
* identification of associated data files;
* identification of any sample tested;
* test results and acceptability; and
* preliminary conclusions.

All pages in the scientific notebook will be sequentially numbered and indexed in the table of contents. Pages which are left blank will have a line drawn diagonally through the blank area with the initials and date the individual performed this step. When not in use, scientific notebooks will be stored in a suitably secure location (e.g. a locked office cabinet).

Scientific notebooks will be reviewed for technical (accuracy and completeness) and record keeping quality by a competent independent technical individual. Independent is defined as a person other than the one who recorded data in the notebook. The reviews, including the name of person(s) performing the review, the date(s) of the review, and the elements of the review, will be documented and become part of the project records.

For any project the format of the documents should be in a logical order to maximize usefulness. In a case where this results in confusion regarding the location of requirements, a "locator page" may be created to help. Each RMPP and SOP or other QA document and subsequent revisions shall reside in the project files, with the QA staff, and with all project participants, as applicable.

8.2 QUALITY ASSURANCE RECORDS

Records that furnish documentary evidence of quality and/or specify quality requirements and will become QA records shall be specified by the Project Leader for each study. The Project Leader shall also define at what point a document or record becomes a QA record and how QA records will be stored, preserved, and disposed of. All documents shall be legible, identifiable, and retrievable. QA Records often include the following:

* Individual documents that have been completed, approved, and that furnish evidence of the quality and completeness of data, and activities affecting quality.

* Documents prepared and maintained to demonstrate implementation of quality system activities; for example, audit, surveillance, and inspection reports.

* Procurement documents.

* Other documents, such as RMPP□s, SOPs, scientific notebooks, correspondence, documentation of telecommunications, specifications, technical data, books, maps, papers, photographs, and data sheets.

* Digital media.

* Other materials that provide information concerning data and document quality, regardless of the physical form or characteristic.

Normally a QA record is a document that will either receive no more entries, or for which immediate access is no longer required by project personnel. QA records shall be controlled for a minimum of five years at RMD unless otherwise specified. Baseline inventory and monitoring projects may require a longer period (e.g., twenty years).

8.3 DOCUMENT CONTROL

Each RMPP will address the manner in which it will accomplish the document control requirements. The RMD Project Leader will identify the documents that are to be controlled and the individual(s) responsible for preparing, reviewing, and approving controlled documents.

Controlled documents that specify quality requirements or prescribe work activities, including revisions thereto, will be reviewed for adequacy, correctness, and completeness prior to approval and issuance as controlled documents. The review should be performed by a technically competent individual other than the originator.

The distribution and use of controlled documents and forms, including changes and editorial corrections thereto, will be controlled to ensure that project staff use only the most current revisions and that a record is established showing when various changes in plans and procedures may affect the quality of project data. This particularly important when changes have been made to SOPs or field data collection forms. Documents used to perform work will be distributed to affected personnel and used at the work location.

The following plate is commonly used to identify controlled documents.

Document ID, such as file name
Revision No.
Date: , or Effective Date
Page___ of___

"Revision number" is the numeric representation of the approved protocol revision. The original unrevised version should be numbered 0. The "Date" should indicate the date of the revision. Effective date is the date

that the document actually becomes effective.

If an activity cannot be performed as defined in the RMPP or SOP(s) and the normal change process would cause unreasonable delays (significant impact to cost and schedules), then an expedited change may be made at the work location by the RMD Project Leader, assuming that the change does not create significant increase in risk to data quality. An evaluation of the work affected by the expedited change will be performed to assess the impact on quality if the normal review process results in a change that is different from the expedited change. This evaluation will be documented. RMPPs may define exceptions to the change process requirements in cases where no risk is afforded the quality of the project data, for example spelling errors, typos, and title changes.

SECTION 9.0

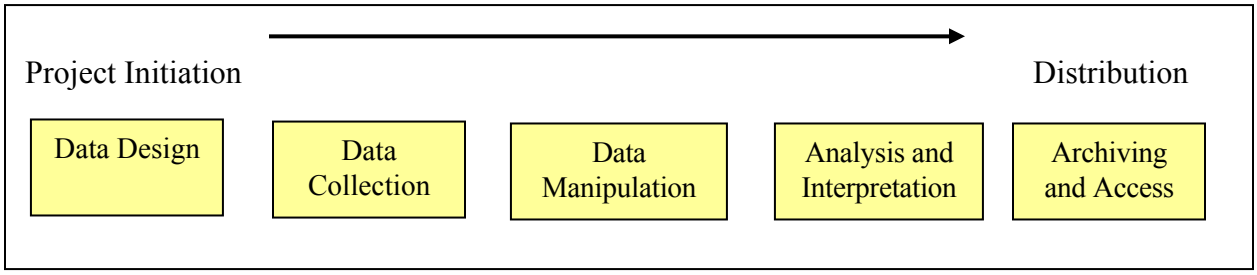
COMPUTER HARDWARE AND SOFTWARE

Computers are involved with almost every aspect of environmental data collection. The objective of this section is to describe the process of quality assurance for data management activities at the RMD. Computer hardware that is purchased must be selected to meet technical requirements and quality expectations. Computer software that is purchased or developed must also provide the functionality required including an ability to conform to National Park Service specifications.

9.1 DATA FLOW

Data management is an integral component of all parts of an environmental data collection effort. The flow of data from project initiation to project completion is shown in Figure 3. Each of these phases requires the use of computers and computer software. During project design, computer programs are used to develop a project sampling design and to develop a database for storing data as it is collected. Field computers or automatic sampling systems are often used to record data. Computers are used to review, verify, validate and store the data in the database. Computer programs are then used to synthesize the data into meaningful information. Computer models are often used to extrapolate results to other locations or time periods. The data and associated information are then made available to others and archived for long-term protection. Through all of these steps, computer hardware and software must be quality controlled to ensure that data and associated information are not corrupted or lost.

Figure 3. Components of data management (adapted from Brundt, 2000[2])



9.2 COMPUTER HARDWARE QA PROCESSES

The first step towards ensuring that computer hardware meets quality expectations is to develop specific technical requirements. For field data computers, these requirements may include light weight, wide operating temperatures, shock resistance and waterproofing in addition to technical capabilities such as memory and processing speed. Computers available on the market can then be compared against these criteria to aid in their selection and purchase. As each available product may have different strengths and weaknesses, it is important to weigh the technical requirements to identify those that are most important to the selection process. Testing may also be required to ensure that the new computers are compatible with legacy software programs that may have been developed for ongoing data collection activities.

As new computers are purchased, clear standard operating procedures should be prepared for the staff using and maintaining the equipment. These procedures must include a process for data backup on a routine basis.

9.3 COMPUTER SOFTWARE QA PROCESSES

As with computer hardware, the first step in the selection of computer software should be the identification of user requirements. Whenever possible, software programs should be selected to conform to current NPS standards. These programs should be updated when the NPS recommendations change. The NPS data management framework is presented in Section 9.5.

Specialized computer software programs may need to be developed for data collection or processing activities. The development of these programs should follow a software development life cycle (SDLC) approach. All software that is developed must be tested to verify that it is accomplishing its intended use and that it meets the requirements of the end user. Each program should be adequately documented to allow for maintenance and updates.

9.4 CHANGE MANAGEMENT

The computer hardware and software capabilities are rapidly changing and evolving. Experience has shown that important legacy data from environmental programs can be lost if care is not taken to maintain these data and transfer them to the most current data management system.

Individual data are also susceptible to change as they are used and reviewed by project scientists. For this reason, a change management process needs to be incorporated in environmental data bases to document when a data value is changed, why it was changed, the old value, the new value, and the individual who made the change.

9.5 NATIONAL PARK SERVICE REQUIREMENTS

The NPS has developed several recommendations to assist staff with the development of databases for inventory and monitoring programs. These are detailed in Table 2.

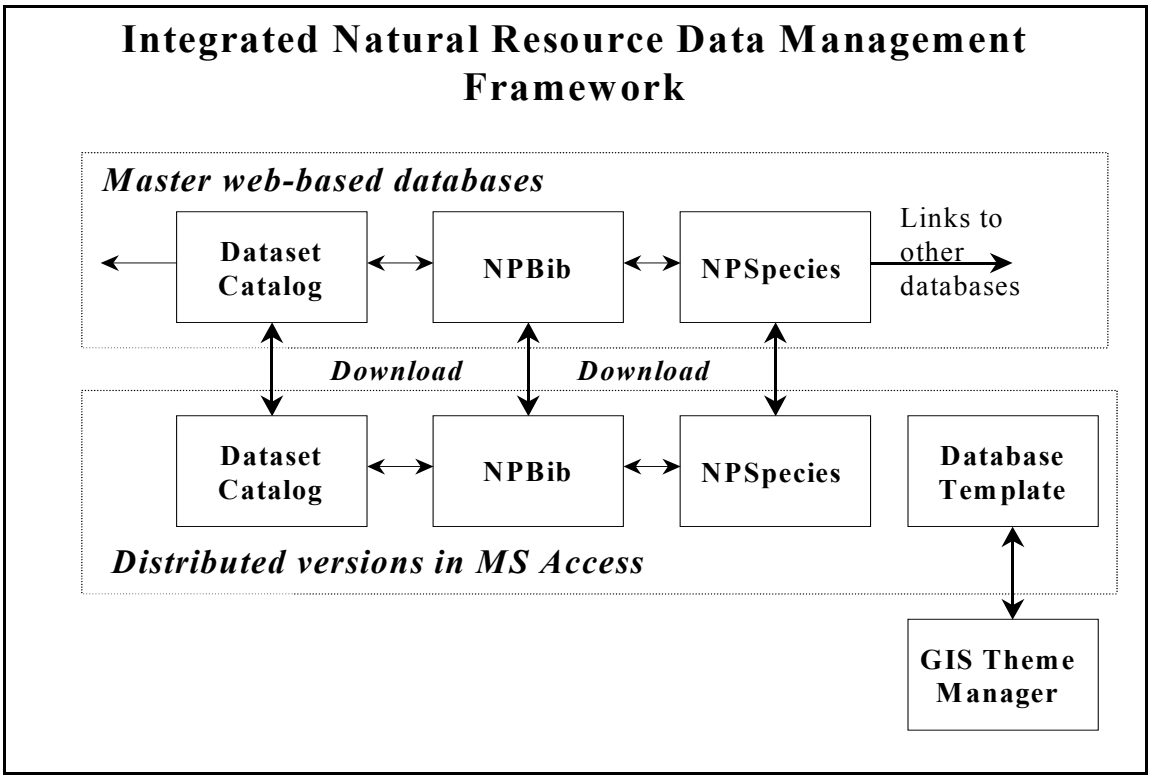
Table 2. National Park Service Database Specifications

Topic	*Specifications*
Descriptive Document	Each database will be submitted with a descriptive document containing information about the project and data.
Database Template	Each database will contain the core database template tables. All other tables will be related to one of the core tables.
Data Normalization	Each database will be optimized to Third Normal Fom. Each table contains data about a single subject and is identified with a primary key. No table contains repeating fields or redundant data.
Naming Standards	Each table and field name will match the corresponding standard format and adhere to the standards defined for root names.
Primary Key	Each table in the database will be identified with a primary key.
Field Description	Each field in the database will be defined by a clear and concise description.
Data Storage	Formatted text will not be stored in the database except in description or comment fields.
Required Fields	Each table in the database will be identified with required fields.
Field Domain	Each field in the database will be identified with an appropriate

	domain.
Field Formatting	Each field in the database may be assigned formatting options for input and/or display.
Data Verification	The data in each database will be reviewed and corrected using an approved data verification method, such that data accuracy is 95% or greater. The description of the verification method and results will be included in the Descriptive Document accompanying the database.

The NPS has also developed an integrated natural resource data management framework (see Figure 4). System-wide databases form the core of this network and are designed to be accessible on the internet. Individual parks are provided with Access programs that can then be used to upload data to the system-wide databases.

Figure 4. Integrated NR Data Management Framework



9.6 ROLES AND RESPONSIBILITIES

The responsibilities of LAME staff towards the development and maintenance of data management systems in the RMD is detailed in Table 3. Additional details regarding responsibilities can be found in Appendix 6 of Landis and Palmer (2002). [4]

Table 3. Data management responsibilities of LAME staff regarding RMD datasets.

Data Personnel	*Responsibilities*
LAME Computer Support Staff	Are responsible to service, install and maintain computer hardware and software, including network systems. They have full authority in issues of system compatibility, configuration standards, hardware, software, and security.
RMD Data Manager/ Archive Technician	Is responsible for the master and archival datasets, data security, data access and dissemination, maintenance of data documentation, and assists with overall database design and standards issues.
Project Leaders	Are responsible for designing statistically sound data collection schemes, adhering to accepted scientific standards, maintaining quality control at all phases of the work, and developing and reporting from their datasets.
Field and Lab Personnel	Are responsible to project managers and assist with the general design, data collection, analysis, interpretation and reporting of natural resource research and management projects.

SECTION 10.0

PLANNING

The RMD Project Leader is responsible for planning all work to assure it is conducted and verified in accordance with project requirements. Planning will be performed and documented in a Resource Management Project Plan (RMPP) or other documents designated by the Project Leader to ensure work is accomplished under suitable controlled conditions.

It should be noted that any and all QA documents and procedures must be useful to the project personnel in attaining the desired data quality. It is a waste of resources to compose a procedure or document that is intended only to satisfy a bureaucratic requirement. Therefore, prepare any and all QA documents in a brief and concise manner.

10.1 RESOURCE MANAGEMENT PROJECT PLANS

RMPP□S are to be written by the RMD Project Leader or designee and have the approval of the Division Chief and RMD QA Manager. The Division Chief may also request the participation of other division staff in the review process for a plan. The RMPP□s should be prepared using the following outline:

Resource Management Project Plan Outline

Title: What is the title of the project?

Team: Who is the project lead and who are project participants?
What academic degrees or specialized training have they received?

Background:

- Purpose: What is the purpose of the project?
- Objectives: What are the project objectives?
- Audience: Who is the principal audience for the project?
- Related Work: List any related data sets or reports that could be documented for cross-reference.

Approach:

- Collection: Will the data be developed primarily through:
  a) Field visits?
  b) Remote instrumentation (*i.e.* temperature recorders, etc)?
  c) Existing data sources (please list)?
- Design: Where will the data be collected?
- Timeline: What is the anticipated time period in which the data will be collected?
- Methods: Briefly summarize your field and laboratory methods (cut & paste from other documents! If you used existing protocols or methods, list the references).
- Species: What species or communities will be examined?
  a) Will you be collecting any specimens and removing them from the site?
  b) If so, what, how many and what will be their disposition?
- Taxonomy: Will you use a taxonomic authority or field guide for identification? If so, what is the reference?
- Exclusion: Will you exclude anything from your data collection? (*i.e.* stems less that a

certain diameter or streams without surface flow)

Results:

Use: How will the collected data be used?

Publishing: Will the data set (or resulting analysis) be published or part of a larger publication? If so, what will the reference be?

Summary: How do you plan to summarize your data?

Models: Will you use a model or other analytical tool to develop your dataset? If so, what is the reference?

Restrictions: Are there legal restrictions on who may use the data?

Data Management:

Owner: Who will be the originator(s)/ owner of the data collected during the project? (Include address and telephone number)

a) If someone else will collect data, please list the name(s), address, and telephone number.
b) Are there other organizations or individuals who should get credit for support, funding, or data collection and analysis?

Form: What will be the form of your data set? - (spreadsheet, ascii file, gis layer, database, other) Why this form?

Filename: What will be the filename for your data set?

Fields: For each file or table, list the fields in the data set and for each field list:

a) The definition of the field
b) If the data will be coded, list the codes and the definitions
c) If the codes come from a published code set, list the reference.
d) If the data are measured, list the units and the minimum and maximum allowable values ("no limit" is acceptable).
e) Otherwise, the domain is unrepresentable. Include a brief description of what is in the field

Collection sheets: Please attach a copy of all draft data collection sheets.

Updates: Will the data set be updated? If so, how frequently?

Archive: Where will your data set be archived (short-term and permanent)?

Keywords: List some keywords to help search for this data set?

Advice: Do you have any advice for potential users of the data set?

Distribution: What are your distribution instructions, if any?

GIS Data: Will this be a GIS data set? If no, skip to next question.

a) Where will the data be accessed?
b) What are the projection parameters?
c) List any source data sets you expect to use. For each source list:
    i. Source name, originator and publication date
    ii. Source time period and scale
    iii. Source presentation form and media type
    iv. Contribution of source to your analysis
d) List the processing steps you will use to create your data set, including the approximate date of processing.

Quality Assurance:

MQO's: What are your measurement quality objectives for each parameter of measurement? (If these are included with the methods, simply refer to the

methods section)
Training: What is your plan for training and certifying data collection staff?
Audits: When do you plan to audit your field crews? If available, attach field audit form.
Data Checking: What measures will you take to make certain that your data set is as nearly correct as possible? (i.e.- data review, verification, validation)
Quality Assessment: How do you plan to assess the quality of your measurements?

Budget: Attach a draft budget for the project.

10.2 MEASUREMENT QUALITY OBJECTIVES (MQO's)

During the preparation of the RMPP, each of the required measurement parameters will be identified for the project. An important step in the quality assurance planning process is to develop performance criteria by which the quality of these measurements can be judged during quality control and quality evaluation activities. For the purposes of this document, these performance criteria will be called measurement quality objectives or MQO's.

An MQO is evaluated through replicate measurements of a parameter of interest. For example, a set of measurements taken by a field-crew member for a given parameter at a training session might be duplicated by the trainer. In order to be certified in this procedure, the trainee would be required to be within tolerance limits for that measurement a certain percentage of the time. During the field season, an auditor might visit that same field-crew member and undertake a number of replicate measurements to determine if the quality of the measurements is acceptable. A quality assurance crew might revisit a plot and independently obtain a set of replicate measurements for the parameter. In each of these situations, it is important to have a standard or MQO for evaluating the degree of acceptability of the data.

Measurement parameters have different characteristics and therefore may require different approaches to setting MQO's. The following table (Table 4) provides some examples of different types of measurement quality objectives.

Table 4. Examples of measurement quality objectives

Example	*Parameter*	*MQO*
1.	Species identification	95% agreement
2.	Condition class (scale of 10 classes)	90% agreement +/- 1 class
3.	Length	80% agreement +/- 4 mm
4.	Width	90% agreement +/- 20%
5.	Chemical concentration	Detection limit 1 mg/L Transition Value: 20 mg/L Precision: +/- 5%

The MQO's for measurement parameters that are classification variables such as species identification or animal gender are generally set as "% agreement" as in example #1. The degree of agreement represents the frequency with which two or more replicate measurements of the same object should agree. Some measurements require the observer to select a class as shown in example #2. Other measurements are continuous and tolerances can be established in terms of absolute values as in example #3. It should be recognized, however, that continuous variables are often more difficult to measure with

an absolute tolerance as the value for the measurement increases. In this case, the MQO is often expressed in terms as a percentage rather than an absolute value (see example #4). Sometimes, it is necessary to combine these two types of MQOs to cover the entire expected range of measurement. Example #5 depicts a situation where below a transition value of 20 mg/L, one would expect a precision of 1 mg/l, but above that concentration one would expect a precision of +/- 5%.

10.3 DATA COLLECTION EFFORTS BY OUTSIDE INVESTIGATORS

Researchers from outside of LAME often request permission to collect natural resource data within the Park boundaries. To encourage adequate planning that results in high quality, useful, accessible and long-lived data, the RMD Division Chief should require that investigators submit a RMPP or equivalent planning document prior to data collection.

Data collected through these efforts should be made available within two years of project completion to be incorporated into the LAME RMD database. Prior to incorporation, independent review of these data should be conducted by LAME staff to ensure data quality.

SECTION 11.0

IMPLEMENTATION OF WORK PROCESSES

Individuals conducting measurements must be provided with detailed procedures and training regarding how those procedures are to implemented. Training should include procedures for recording data including the calibration and maintenance of equipment.

11.1 STANDARD OPERATING PROCEDURES

The RMD Project Leader is responsible for identifying standard operating procedures (SOPs) which will document instructions for repetitive activities.

SOPs must contain, as appropriate:

* test prerequisites, such as test equipment verification and calibration, special controls, precautions, environmental conditions, and process parameters;
* instructions for addressing accuracy, and precision of the results (duplicates, surrogate recoveries, check samples);
* a sequential description of the work to be performed including controls for altering the sequence of required operations;
* special qualification and training requirements and/or skills;
* verification points and hold points;
* quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished;
* the records to be generated by the implementation of the SOP;
* information to be recorded in the scientific notebook or on data forms;
* provisions for documenting deviations from procedures; and
* provisions for recording expedited SOP changes.

In addition the SOPs must contain, as appropriate, provisions for documenting directly or by reference the:

* equipment used, including manufacturer, model, and serial number;
* data acquisition system used, including computer hardware and software title and version;
* identification of data files;
* item tested;
* date of test;
* tester or data recorder;
* observations;
* test results and acceptability;
* verification of calculations;
* action taken in connection with any deviations noted; and
* person evaluating test results.

SOPs must be available at each instrument or work area so that operators will have them available for reference while working.

11.2 TRAINING AND CERTIFICATION

The development of SOP's alone does not guarantee that high quality data will be collected. A training program assists field and laboratory staff to obtain a clearer understanding of data collection procedures described in the SOP's. Training sessions should be held prior to the initiation of routine data collection and should include a process for certifying that trainees have understood and can perform the data collection procedures.

Data collection programs that span several years or require the participation of a large number of field staff should consider the development of training manual. A suggested outline for a training manual is provided in Table 5.

Table 5. Recommended outline for a training manual

Outline Topic	*Explanation*
1. Course Objectives	Describes specific measurement activities that a trainee should be able to conduct after completing the training course.
2.Lesson Outline	Describes the time allotted for each component of the training session
3. Preparation Activities	Describes requirements to prepare for the training session such as training site selection, equipment and materials, staff orientation, and classroom and field site set-up.
4. Lesson Plan	Details specifics of training program for the classroom and the field and/or laboratory training activities.
5. Certification Tests	Describes certification questions and measurement activities

The following suggestions are provided to assist project leaders with the planning of training sessions:

* Allow adequate time for training in case of bad weather or the need for retraining.
* Allow time to provide an overview of data collection program and its importance.
* Provide suggestions for a daily or weekly schedule of data collection activities.
* Devote adequate time to safety training.
* Include a review of the quality system and the importance of each of its components.
* Stress the importance of collecting additional information as notes that can be of benefit in interpreting results or accessing research sites in future years.
* Select field-training sites that represent as much as possible the range of conditions found by field staff during a data collection season.

11.3 IDENTIFICATION AND CONTROL OF DATA

11.3.1 Identification of Data

Data shall be identified to assist in the determination of their correct use. Identification of such data shall be provided in all documents, information systems, or both, in which such data appear. Identification shall be sufficient to provide traceability to other components of the project, such as log books, instrumentation, and analyst.

The raw data shall include a reference to the origin of the data (project name), name or initials of the data generator (e.g., the analytical instrument operator), the date, the instrument or other means of generation. Control measures shall be established and implemented to assure that data are identified properly. These measures shall include verification of the identification of such data prior to release for use.

All data prepared from raw data shall be referenced to the raw data by file name, date, or other means, such as scientific notebook name.

11.3.2 Control of Data

Copies of reports and deliverables are to be submitted to the RMD QA manager. Other requirements for data control may apply as well. For example, all project data must be traceable and retrievable. This means that in addition to being able to locate and retrieve all raw data, log books, and reports, an investigator shall be able to trace calibrations and QC back to the sources of reagents and other materials. All laboratory standards shall be traceable to the National Institute of Standards and Technology (NIST) whenever possible.

11.3.3 Curation

All data produced and/or processed by the RMD will be maintained in files for a minimum of five years, unless otherwise specified. Upon termination employees must submit their data files to their supervisor or Project Leader. Upon completion of a task, subtask, or project, all raw data will be controlled by the Project Leader or his designee in a manner that preserves the integrity of the data.

11.4 IDENTIFICATION AND CONTROL OF SAMPLES

Procedures shall be developed and implemented as required and specified in the SOP to ensure that samples are identified and controlled in a manner consistent with their intended use. Procedures shall define the responsibilities (including interface between organizations) for collection, identification, handling, storage, transportation, and the generation of sample records.

11.4.1 Identification

Physical identification shall be used. All identification (labeling) methods shall be traceable to the appropriate documentation, such as field or laboratory notebooks and raw data. Measures shall be taken to maintain sample identification in storage that is consistent with the planned duration and conditions of storage, and they shall describe actions to be taken where samples may have a maximum life expectancy.

11.4.2 Storage

Storage methods shall be developed and implemented to insure (within the limits of technology and resources) that samples are maintained in conditions that assure they do not degrade. Physical segregation of samples to preclude cross-contamination shall be used. Sample treatment and storage requirements shall be defined in the appropriate SOPs and shall include storage during transport when necessary.

11.4.3 Control

Controls shall be developed and implemented to assure that sample identification is verified and maintained when handled, transported, or transferred from one work station to another, such as from the field to the laboratory. When required, chain-of-custody procedures and documentation will be developed and followed.

11.4.4 Curation

In a case where sample volume remains after processing, provision must be made for curation or disposal of these residuals.

11.5 CALIBRATION AND MAINTENANCE OF EQUIPMENT

Measures shall be established to insure that field and laboratory equipment such as thermometers, analytical balances, pH meters, instruments, and other measuring and test equipment used in activities that affect quality are controlled, calibrated, and adjusted properly at specified periods to maintain accuracy within necessary limits. SOPs shall be composed where necessary as specified in individual RMPP□s for the proper use of these devices.

Equipment shall be calibrated against certified standards having known valid traceability to the National Institute of Standards and Technology, or to other nationally recognized standards if available. Equipment shall be calibrated, adjusted, and maintained at prescribed intervals. If no nationally recognized standards exist, the basis for calibration shall be documented.

The method and interval of calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy and precision, intended use, degree of usage, and other conditions that affect measurement control. Measuring and test equipment must be labeled, tagged, or otherwise documented, in a fashion that indicates the due date of the next calibration.

Measuring and test equipment shall be handled and stored properly to maintain accuracy. If measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of previous results obtained, and of the acceptability of items previously inspected and tested, or data gathered since the last calibration. Devices that are out of calibration shall be tagged or segregated, and they shall not be used until they have been recalibrated. If any measuring or test equipment consistently is found to be out of calibration, it shall be repaired or replaced.

Records shall be maintained, and equipment suitably marked to indicate calibration status. Records shall be maintained for daily/weekly routine calibration checks as well as for annual or semi-annual calibrations. Calibration records shall identify the calibration procedure utilized to perform the calibration.

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial equipment provides adequate accuracy.

11.5.1 Control of Out-of-Calibration Equipment

Monitoring, measuring, testing, and data collection equipment will be considered to be out-of-calibration if any of the following conditions exist:

* The calibration due date has passed without recalibration.
* The equipment produces results known or suspect to be in error.

Out-of calibration equipment will be controlled. The controls will include the following requirements as appropriate:

* Out-of calibration equipment will be tagged, segregated, or otherwise controlled to prevent use until recalibration. Operator-calibrated instrumentation is controlled through the rejection of data resulting from an out-of-calibration instrument. Rejected data is labeled as such.
* When equipment are found to be out-of-calibration during recalibration, the validity of results obtained using the equipment since its last valid calibration will be evaluated and corrective action taken that is appropriate to the project.
* Recall intervals will be established.

11.5.2 Documenting Calibration of Monitoring, Measuring, Testing and Data Collection Equipment

Documentation of monitoring, measuring, testing, and data collection equipment will include the following information as appropriate:

* identification and description of the equipment being calibrated;
* physical condition of the calibrated item as appropriate;
* date(s) of performance of calibration;
* identification of calibration procedure used, or description of any non-standard method used;
* the name, signature, title of the individual(s) performing the calibration and accepting responsibility of the results and documentation of the calibration;
* special limitations of use; and
* date of next required calibration.

SECTION 12.0

ASSESSMENT AND RESPONSE

This section describes the quality assessment and response activities of the RMD quality system. The overall goal of these QA activities is to ensure that collected data meet the requirements of the end users. Qualitative assessments or audits are used to determine if data are being collected as previously planned and documented. Quantitative assessments or remeasurements are used to evaluate if results are meeting MQO's. The checking, verification and validation of data provides a means for identifying and correcting data errors. Data quality assessments provide the user with an objective means to determine if the data are suitable for their intended uses. Corrective actions in response to quality assessment activities are utilized throughout a project to improve data quality.

12.1 AUDITS

All RMD activities shall be subject to planned and scheduled internal as funded and external audits to assure that procedures and activities comply with the overall quality system description and to determine their effectiveness. Audits will provide an objective evaluation of quality-related practices, procedures, instructions, activities, and items, including the review of documents and records, to insure that the quality system is effective and implemented properly.

The audits shall be performed in accordance with written procedures, using checklists or marked-up procedures as applicable, by the QA staff member or other appropriately trained personnel as necessary.

12.1.1 Audit Reporting

Results of audits performed by the QA staff member are to be reported to the Project Leader with copies to the branch and division chief. Results of audits performed by other RMD personnel are to be submitted to the Project Leader with copies to the RMD Division Chief and the QA Manager.

All deficiencies, nonconformances, and potential quality problems identified during an audit are to be documented and monitored until verification of effective corrective action is made. That is, follow-up action, including verification of corrective action or re-audit of specific areas, shall be performed.

Management of the audited work group shall investigate adverse audit findings and "give credit where credit is due" for good audit findings. In the case of adverse audit findings, the management shall determine cause, schedule corrective action, including measures to prevent recurrence, and within 30 calendars days of receipt of the audit report, notify the QA Manager and RMD management in writing of action taken or planned.

RMD audit reports shall be signed by the audit-team leader and issued within 14 calendar days after the audit has been conducted. The report shall include the following information, as a minimum:

* Scope of the audit.
* Identification of the auditors.
* Identification of persons contacted during audit activities.

* Summary of audit results, including a statement of the effectiveness of the quality system

elements that were audited.

* Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited work group.

12.1.2 Audit Records

As a minimum, audit records shall include the following:

* Identification of the entity or activities, or items audited and individuals contacted during the audits.
* Description of any deficiencies, nonconformances, and potential quality problems identified.
* Audit plans, audit reports, written replies, the record of completion of corrective action, and a summary record of the close-out of the audit.

12.2 REMEASUREMENTS

Quantitative assessments of data quality are also used during a data collection program to determine if measurement protocols are being followed and if MQO's are being achieved for a project. The primary tool for quantitative assessments is the repeating of a measurement or a "remeasurement."

Several different approaches are used to obtain remeasurement data. For observational data from the field, three types of remeasurements should be conducted.

1) During an audit, QA staff should independently collect a subset of data that the field crew is collecting. These remeasurement data can then be immediately compared to the routine field crew data to identify procedural errors and to determine if MQO's are being met. This type of remeasurement data is often called a "hot check."

2) After a field crew has collected a data set for a field site, QA staff can revisit the field site and review the results of the field crew. Any data collection errors such a missed data, improperly labeled data, or data outside of acceptable tolerances are identified and reported. This type of remeasurement of data is often called a "cold check" and is frequently used as a means of performance evaluation and certification for payment to contract crews.

3) QA staff at field sites should also collect remeasurement data without having the original field crew's results "in hand." The primary purpose of this type of remeasurement is to document of overall quality of the data collected from a project. This type of remeasurement is termed a "blind check" as both the data from both the original field crew and the QA staff are collected independently.

The number of remeasurements required in a project will depend of the scope and budget of the project. During the development and testing phases of a project, remeasurement of approximately 25% of the field sites may be required. During long-term implementation of a project, approximately 10% of field sites should be remeasured for quality control or quality evaluation purposes.

When obtaining samples from the field, remeasurement data are obtained by collecting duplicate

samples. Field duplicates should be collected by the routine crews or by the QA staff and forwarded for analysis to the laboratory. These samples are useful in the evaluation of overall data quality. Additional samples with known concentrations of analytes (performance samples) should also be provided to document data quality and identify problems with the measurement system.

12.3 DATA REVIEW, VERIFICATION AND VALIDATION

The RMPP should describe specific criteria for the acceptance or rejection of data as well as procedures for the determination of outliers and for flagging data. Since in some research it is not always possible to predict such criteria, the QA plan may express the intent to develop these criteria as the methods for data review are developed. Critical control points should also be described. All data reports shall be reviewed by the Principal Investigator, and the QA staff, if applicable before they leave RMD. No data or reports are to leave RMD without the consent of the applicable RMD Project Leader. In some cases, the RMD Chief must approve data release as well. These requirements should be specified in the RMPP.

As data are collected, they need to be reviewed to ensure that the data have been recorded and transmitted correctly to the database. This is accomplished by checking for transcription errors or invalid field codes. In addition, additional steps should be taken to have the data statistically and scientifically checked for data errors. An example of a statistical evaluation is outlier detection. Values identified as outliers by these procedures should be closely scrutinized as to their accuracy. Results that one would scientifically expect to be highly correlated with other measured values can also be evaluated as to their internal consistency to identify suspect data. When these evaluations are conducted by those collecting the data, it is termed data verification. When someone external to the data generator conducts these evaluations, it is termed data validation.

In additional to the verification of individual data results, the RMPP must address verification of any of the processes that are used to reduce or process the data. Verification of the data reduction process itself must be addressed appropriately for the level of effort. Each type of data reduction can be verified against some prescribed methodology in order to assure that errors inherent in data collection, reduction, and processing are corrected.

Verification of computer software or programs requires but is not limited to the following:

* Documentation in the form of a written procedure to accompany the software or program explaining the use of the materials.
* Testing of the software or program using known results, and documentation that the test was successful.
* A label and traceability system to prevent any modified software from being used in a manner that is believed to be unmodified.
* Hand calculation.
* Comparison of raw data to entered-digitized data.

12.4 DATA QUALITY ASSESSMENT

Data quality assessment tells the investigator if the project data satisfies the quality objectives. Assessment involves the calculations given in this section, plus other pre-planned statistical treatments,

equations, units, and assessment frequency. The assessment procedures must agree with the quality objectives as described in the MQO's before data comparisons and quality statements can be made. **NOTE:** All data must be assessed for precision, and should be assessed for bias, representativeness, completeness, and comparability. For certain types of measurements, the evaluation of a detection limit is also appropriate. RMD requires that **at a minimum measurement data be assessed for precision**.

Some examples of data quality assessment procedures that may be applicable are:

12.4.1 Precision

Precision is the degree of agreement among replicate measurements. If calculated from duplicate measurements:

$$RPD = [(C_1 - C_2) \times 100\%] / [(C_1 + C_2)/2\}$$

where,

RPD = relative percent difference,
C_1 = larger of the two observed values, and
C_2 = smaller of the two observed values.

If calculated from three or more replicates, use relative standard deviation (RSD) rather than RPD:

$$RSD = (s/ \tilde{y}) \times 100\%;$$

where,

RSD = relative standard deviation,
s = standard deviation, and
$\tilde{y}$ = mean of replicate analyses.

Standard deviation, s, is defined as follows:

$$s = \sqrt{\sum_{i=1}^{n} (y_i - \tilde{y})^2 / (n-1)}$$

where,

s = standard deviation,
y_i = measured value of the i-th replicate,
$\tilde{y}$ = mean of replicate measurements, and
n = number of replicates.

12.4.2 Bias

Bias is the systematic or persistent distortion of a measurement process in one direction. For situations where a standard reference material (SRM) is used:

$$\%R = 100\% \times (C_m / C_{srm})$$

where,

%R= percent recovery
C_m= measured concentration of SRM
C_{srm}= actual concentration of SRM

12.4.3 Completeness

Completeness is the relative amount of valid data obtained from a measurement system.

$$\%C = 100\% \times (V / T)$$

where,

%C	= percent completeness,
V	= number of measurements judged valid, and
T	= total number of measurements.

Completeness can also be defined from a statistical point of view as follows:

$$\%C = 100\% \times (V / n)$$

where,

%C =	percent completeness,
V =	number of measurements judged valid, and
n =	total number of measurements necessary to achieve a specified statistical level of confidence in decision making

12.4.4 Comparability

Comparability is the confidence that two data sets can contribute to a common analysis or interpolation. Comparability is a parameter that is becoming increasingly important in scientific studies as it becomes apparent that many existing data sets cannot be combined to reach a valid conclusion. The RMD therefore requires that studies that must be comparable as required in the respective quality objectives, must have the same experimental protocols. Minor differences among protocols are allowable provided the investigators can prove that the differences will not effect the comparability for that parameter. Protocols, associated modifications and differences, and data usability qualifiers and limitations must be documented.

12.4.5 Detection Limit

A method detection limit is defined as follows for all measurements:

$$MDL = t_{n-1,\ 1-\alpha=0.99)} \times S\ ;$$

where,

MDL	= method detection limit, and
S	= standard deviation of the replicate analyses,
$t_{(n-1,\ 1-\alpha=0.99)}$	= Students' t-value appropriate to a 99% confidence level and a standard deviation estimate with n-1 degrees of freedom.

12.5 CORRECTIVE ACTION

The RMD Project Leader is responsible for assuring corrective actions are identified, documented, and completed in a timely manner. The RMD Project Leader, as necessary, will specify the responsibility, authority, and completion date for implementing and verifying corrective actions.

The planning of all RMD studies will provide for the timely use of corrective action to minimize generation of erroneous data. Corrective action is possible in all phases of a project and can occur anywhere within the QA scheme. This QSMP requires that SOP□s address corrective action for specific quality control indicators that are designed to trigger corrective action as well as other adverse conditions which may affect the quality of the scientific data generated by the project as applicable .

Examples are listed of QC indicators which shall result in corrective action, resolution, and documentation that acceptable data production has resumed. The SOP should specify how such a corrective action should be documented, for example as immediate corrective action with a notation in the associated scientific notebook or via other more formal record such as a report.

SECTION 13.0

QUALITY IMPROVEMENT

13.1 QUALITY SYSTEM ASSESSMENT

Annually, the QA staff shall see that one or more members of RMD management reviews the RMD quality system as described within this document.

Items to be considered when revising the document shall include but not be limited to:

* Project-specific QA problems encountered during the previous year.
* Procurement QA problems.
* Administrative/management QA problems.
* Changes in QA requirements.
* Training.
* Other steps needed.

The QA staff shall revise the QSMP (revised text indicated by italics) and document all other changes to the RMD Quality system with the advice and concurrence of the reviewer(s) and RMD chief. QSMP revisions shall be submitted to the RMD Chief with copies to the RMD Project Leaders and Branch Chiefs.

13.2 IMPLEMENTATION REQUIREMENTS AND SCHEDULE

The implementation schedule after approval of this QSMP is as follows:

RMPPs compositions completed:	Three months from the award of funding for a project
Audits by RMD QA staff member:	As funded, a schedule is to be prepared by the QA staff member and circulated to project personnel.
Quality System Assessment:	Initiated within one year of the revision date of this document.
QSMP revision:	Completed within one month of the completion of the revision draft resulting from the quality system assessment.

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